

PBT Rule Development

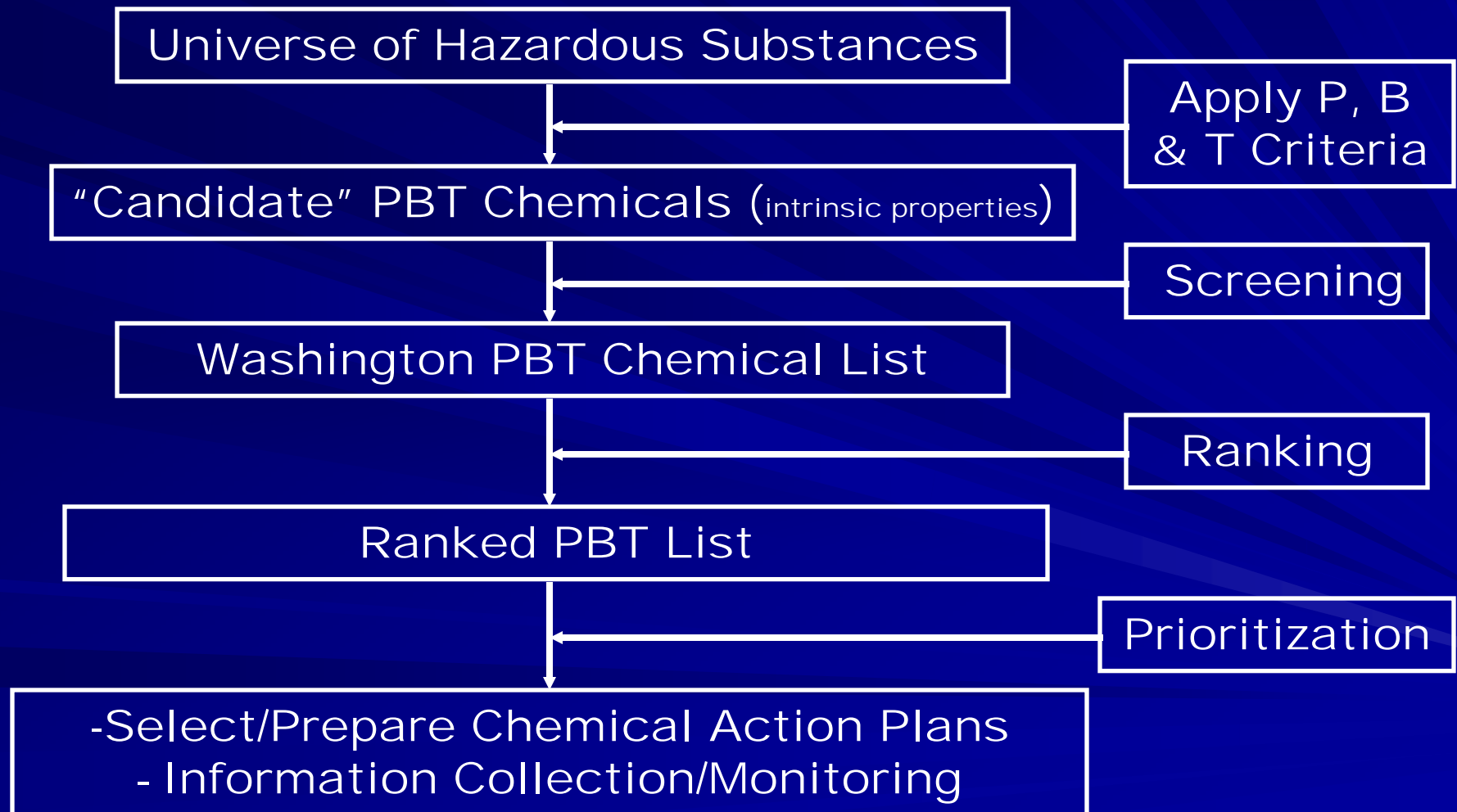
Overview
and
Rationale for Decisions on Selected
Rulemaking Issues

Prepared For
PBT Advisory Committee
November 17, 2004

Draft PBT Rule - Overview

9:15 – 9:45

Building on Areas of Agreement



Summary of Background Documents

- Background Document – Draft PBT Regulation (11-10-04)
- Draft PBT Rule – Chapter 173-333 WAC
“PBT Rule Advisory Committee draft”
(11-10-04)

Areas of Relative Agreement

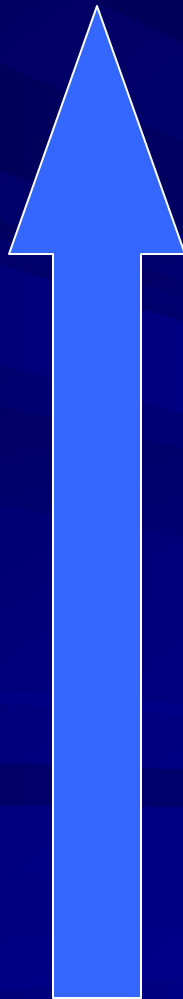
- Characteristics of a “good rule”
- Draft rule outline – provided at Sept. 29 meeting
- Phased approach
- PBT Criteria – P, B, and T
- PBT List – have List in rule and future changes to list via rule amendment. No tiered List.
- Uses of PBT List
 - For PBTs to be evaluated in CAPs
 - Acquire additional information on ambient concentrations
 - Public education
 - Encourage voluntary reduction measures

Key Unresolved Rule Issues

- Long-term Goals
- Relationship to PBT Strategy
- Precautionary Principle
- Purpose of PBT List
- Uses of PBT List
- Selection criteria
- Metals
- Screening factors
- Chemical groups
- Initial PBT List

Underlying Assumptions

**Increasing
Hazard**



- Additional Measures Needed to Prevent Threats to Human Health and the Environment in Washington
-

- Problems/Hazards Addressed Through the Continued Implementation of Existing Programs
-

- No Actions Necessary

Recommendations



Part I

General Provisions

9:45 – 10:45

Section 100

General Provisions

- 100 - Goal and Purpose
- 110 - Applicability
- 120 - Chapter Summary
- 130 - Exemptions to PBT List
- 140 - Administrative Principles

Section 100 - Goal and Purpose

■ Goal:

- The goal of this chapter is to minimize threats to human health and the environment by reducing and, where feasible, phasing out the uses and releases of persistent, bioaccumulative toxins (PBTs) in Washington.

■ Purpose:

- Establish criteria Ecology will use to identify persistent bioaccumulative toxins that pose human health or environmental impacts in Washington State;
- (b) Establish a list of persistent bioaccumulative toxins.
- (c) Establish procedures Ecology will use to review and periodically update the list;
- (d) Establish criteria for selecting persistent bioaccumulative toxins for which Ecology will prepare chemical action plans; and
- (e) Define the scope and content of chemical action plans and establish the process Ecology will use to prepare those plans.

Section 110 - Applicability

- Applies to Ecology, does not diminish Ecology's authority elsewhere
- Provides for public involvement opportunities
- Does not impose new requirements on others
- Describes how Ecology will set priorities in addressing PBTS
- Does not create new authorities nor constrain existing authorities.

Section 120 – Chapter Summary

- Introduction
- What are PBTs
- Identifying and listing PBTs
 - PBT List
 - Criteria for identifying and listing PBTs
 - Criteria for removing PBTs from List
 - Process for adding and removing PBTs from List
 - Public involvement
- Priorities for Caps
- CAPs
- Coordination with other agencies
- Public involvement in CAP development

Section 130 – Exemptions

- Any pesticide registered FIFRA, or any fertilizer regulated under the Washington Fertilizer Act, shall not be included in a persistent bioaccumulative toxin rulemaking process, list, or CAP undertaken by Ecology.

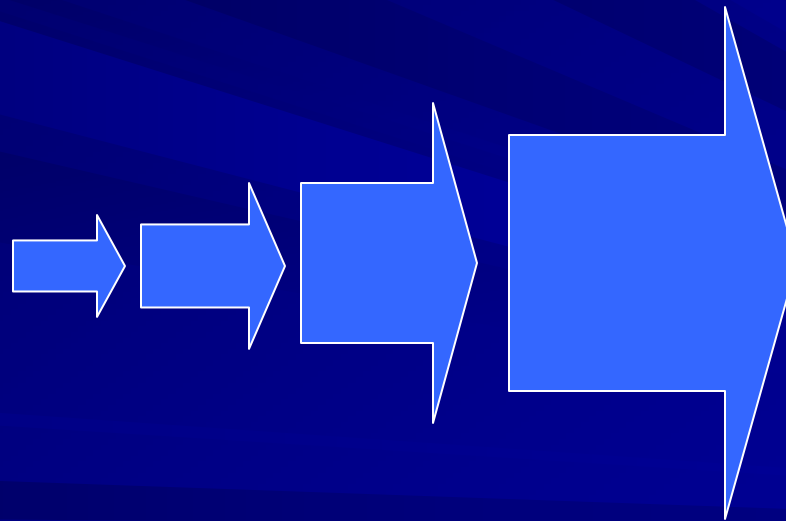
Section 140 – Administrative Principles

- **(1) Introduction**
- **(2) Scientific information**
- **(3) Public involvement**
- **(4) Clear documentation**
- **(5) Predictability**
- **(6) Coordination**

Long-term Goals [Section 100]

Increasing Concentrations

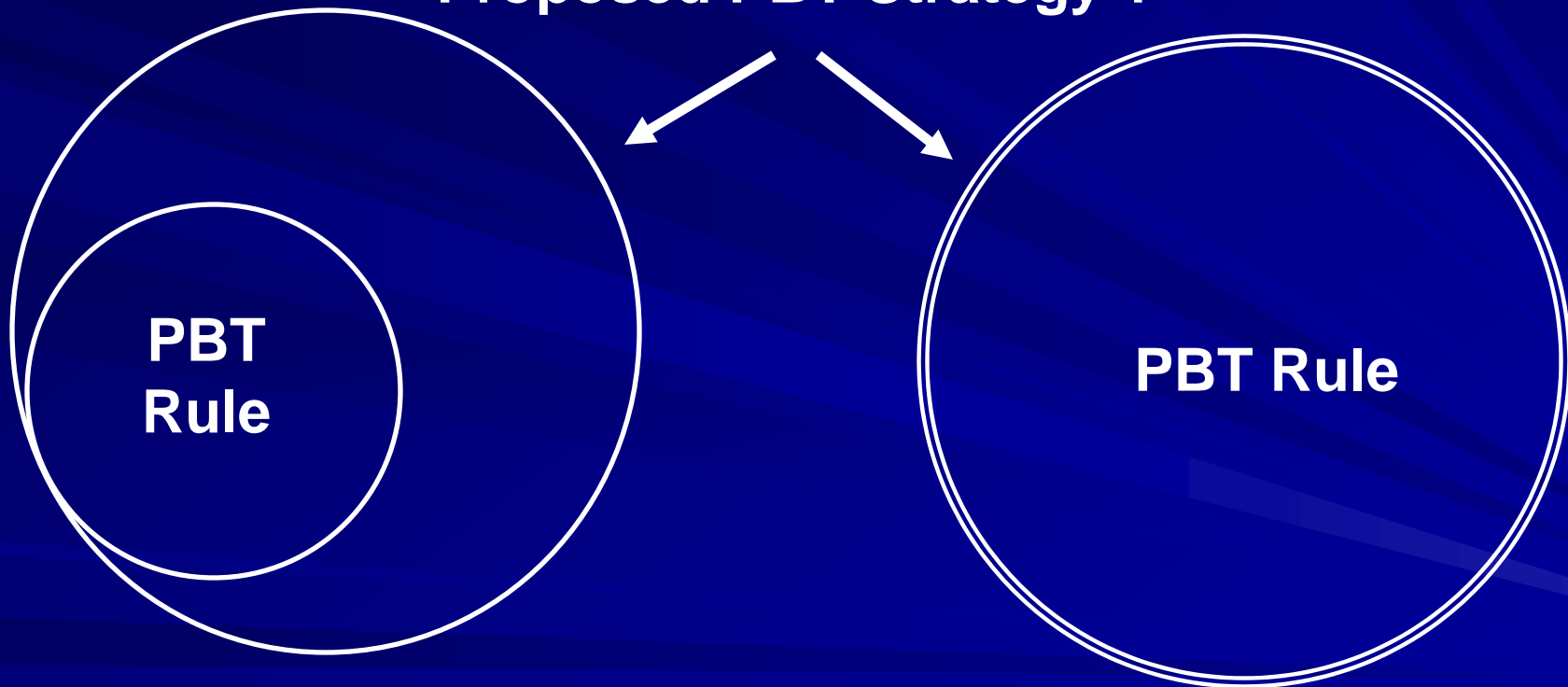
Initial Sources
Low or Undetectable
Concentrations



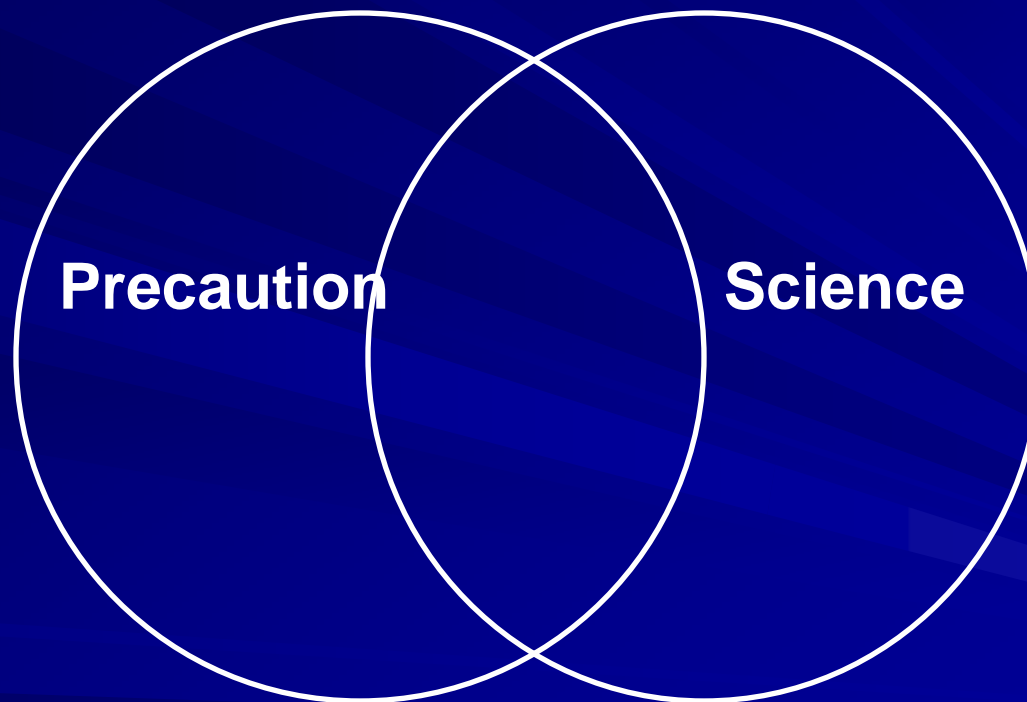
Tissue
Concentrations
Threat to Human
Health and Plants &
Wildlife

Status of Proposed PBT Strategy and Relationship to PBT Rule [Section 140]

Proposed PBT Strategy ?



Precaution in Response to Scientific Uncertainty/Variability [Section 140]



Part II

Definitions

9:45 – 10:45 Continued

Section 200 - Definitions

■ Definitions for:

- Bioaccumulation
- Bioaccumulation factor (BAF)
- Bioconcentration factor (BCF)
- Carcinogen
- Chemicals
- Chemical Group
- Chemical Action Plan (CAP)
- Cross-media transfer of chemicals
- Degradation
- Ecology
- Ecology PBT Strategy

Section 200 – Definitions, cont'

- Environment
- Environmental half-life
- Feasible
- Log-octanol water partition coefficient
- Minimize
- Media or Medium
- Persistent bioaccumulative toxin
- Persistence
- Reduce or where possible eliminate
- Toxicity

Part III

“...Its déjà vu all over again...”

Yogi Berra

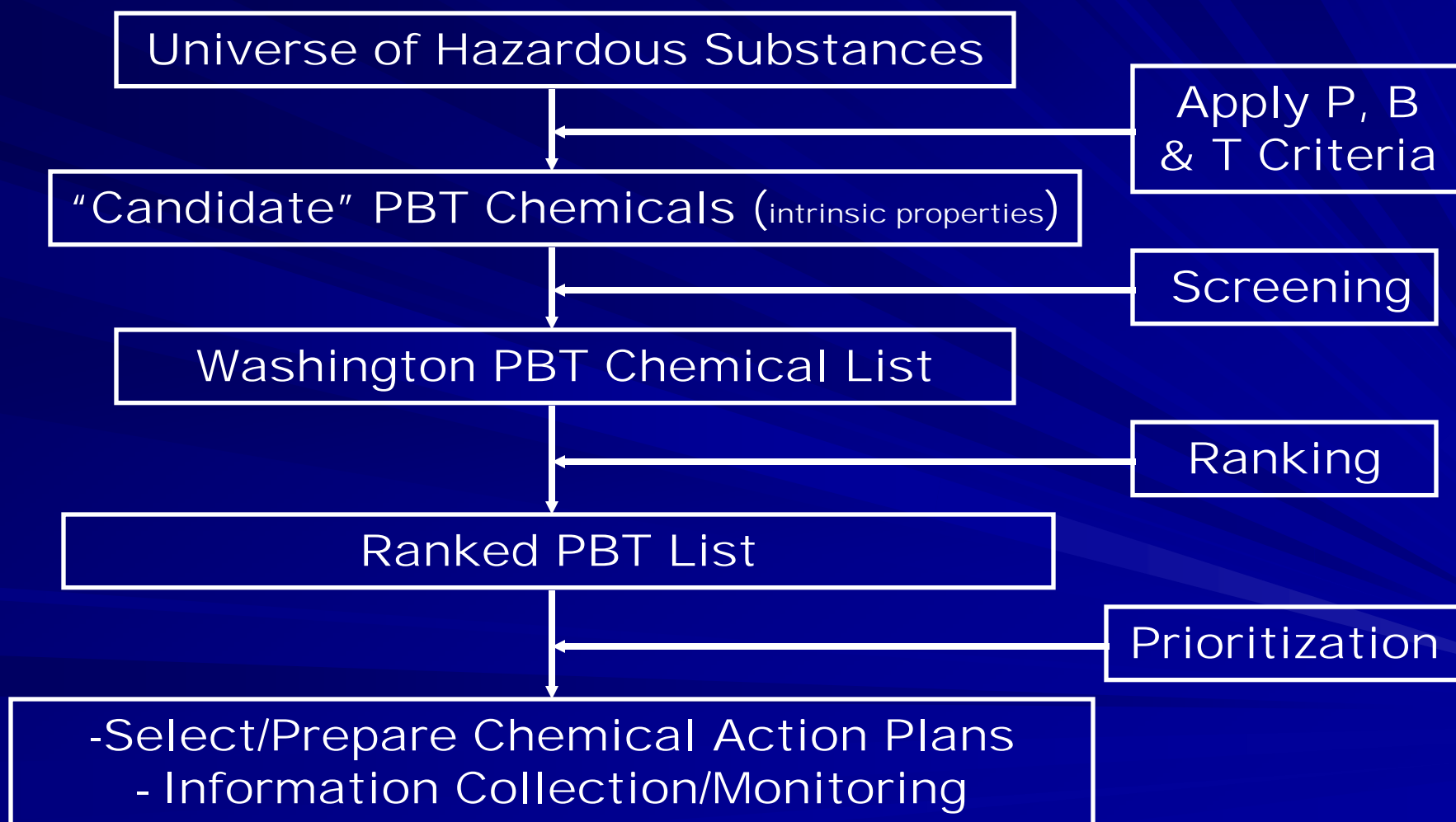
The PBT List and Criteria and
Procedures for Revising the List

11:15 – 1:15

Part III - PBT List and Criteria

"Those who cannot remember the past are condemned to repeat it."

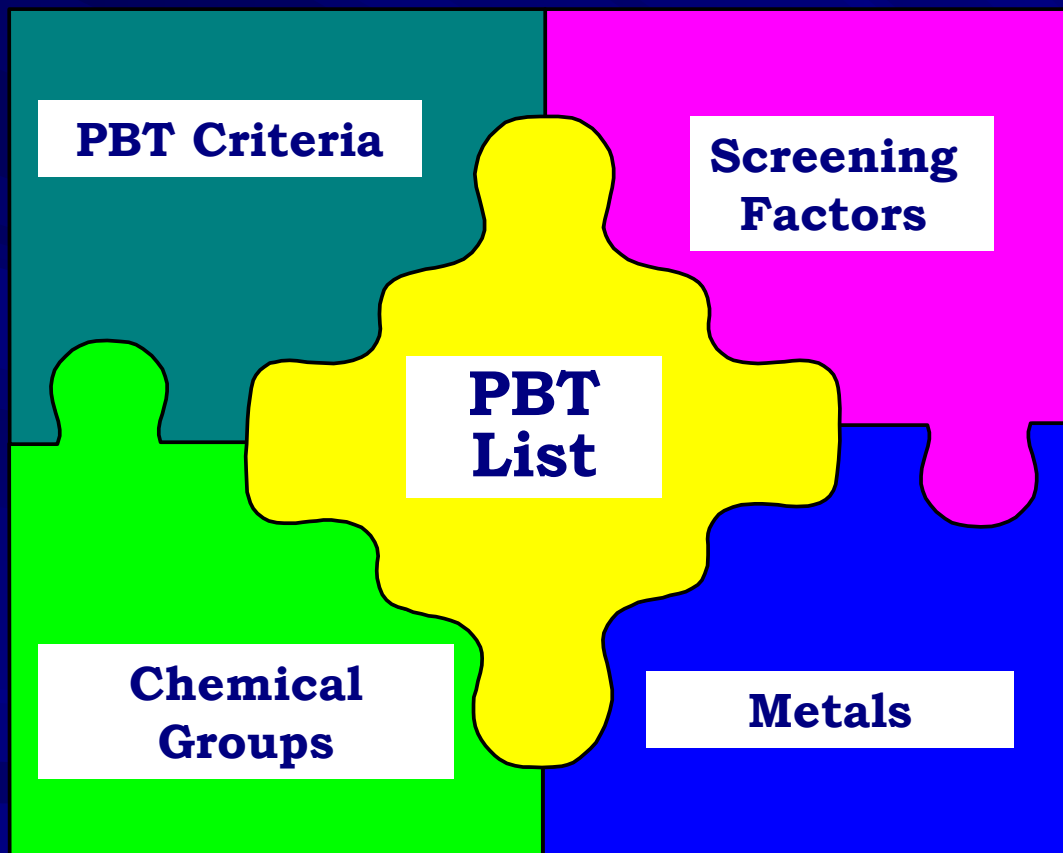
George Santayana



Issues With Wide Range of Opinions

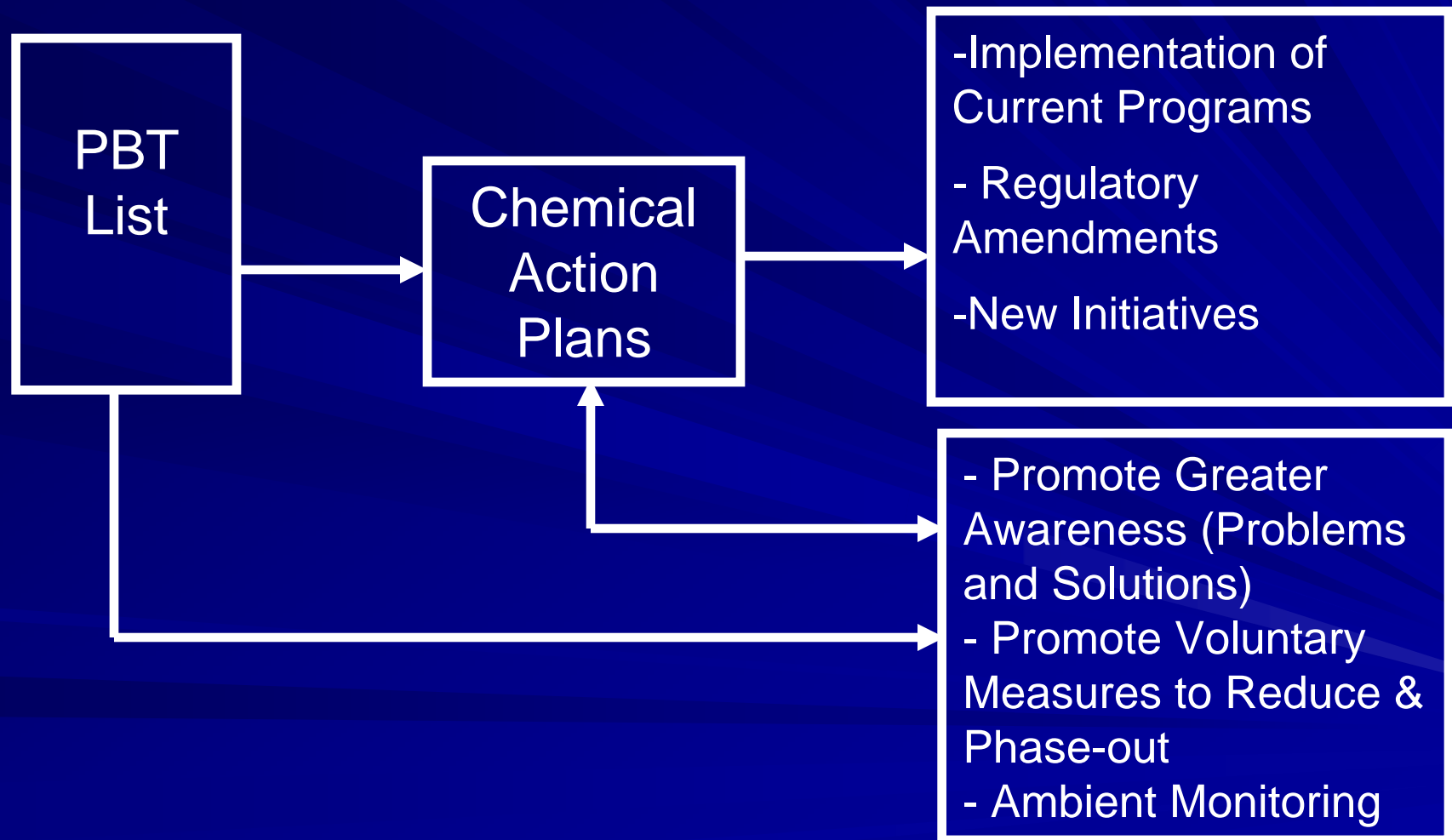
“Work expands to fill the time available”

C.N. Parkinson



WAC 173-333-300

Purpose and Uses of the PBT List



WAC 173-333-320

PBT Criteria and Listing Factors

■ PBT Criteria

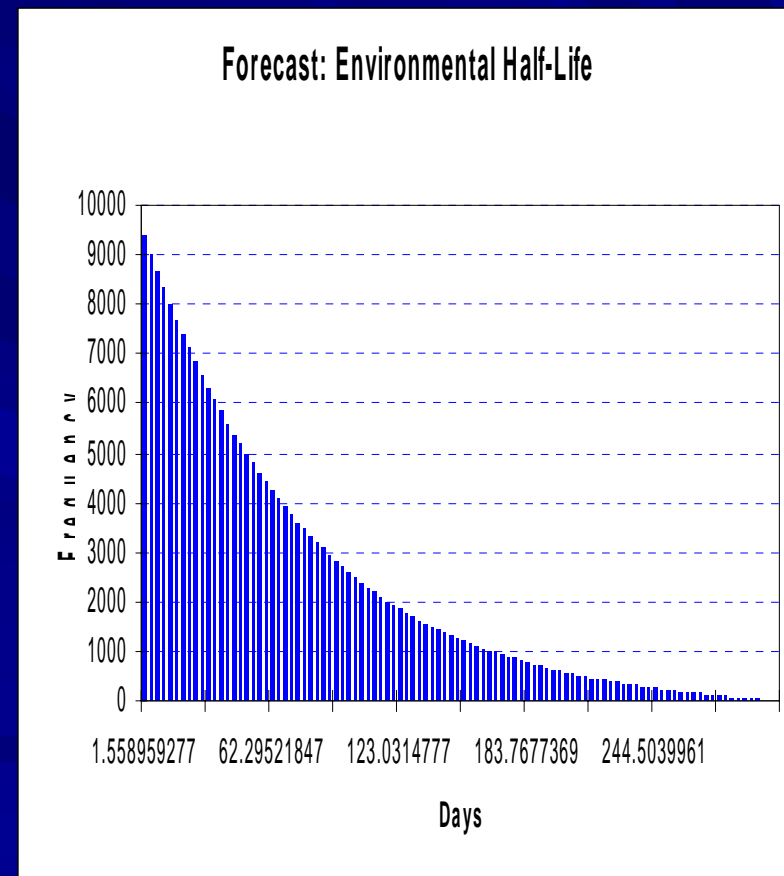
- Persistence
- Bioaccumulation
- Toxicity
- Bioavailability (Metals)

■ Listing Factors

- PBT Criteria
- Use/release/presence in Washington
- Not a registered pesticide
- Not a regulated fertilizer

PBT Criteria Persistence

- Media-Specific Half Life > 60 days
- Rationale:
 - Legislative Direction
 - Scientific Foundation
 - Purposes & Intended Uses of the List & Relationship to Other Criteria
 - Practical Considerations



PBT Criteria

Bioaccumulation

- BAF/BCF > 1000

- Rationale:

- Legislative Direction
- Scientific Foundation
- Purposes & Intended Uses of the List
& Relationship to Other Criteria
- Practical Considerations

PBT Criteria

Toxicity (Non-Cancer Effects)

- Reference Dose < 0.003 mg/kg/day
- Rationale:
 - Legislative Direction
 - Scientific Foundation
 - Human Health Protection
 - Consistency
 - Transparency & Predictability

PBT Criteria Toxicity (Cancer)

- Cancer Slope Factor $> 1 \text{ (mg/kg/day)}^{-1}$
- Rationale:
 - Legislative Direction
 - Scientific Foundation
 - Human Health Protection
 - Consistency
 - Transparency & Predictability

PBT Criteria

Toxicity (Ecological Effects)

- Aquatic Toxicity Value < 0.1 mg/L
- Rationale:
 - Legislative Direction
 - Scientific Foundation
 - Ecological Protection
 - Consistency
 - Transparency & Predictability

Metals

■ Four criteria

- Persistence
- Bioaccumulation
- Toxicity
- Bioavailability

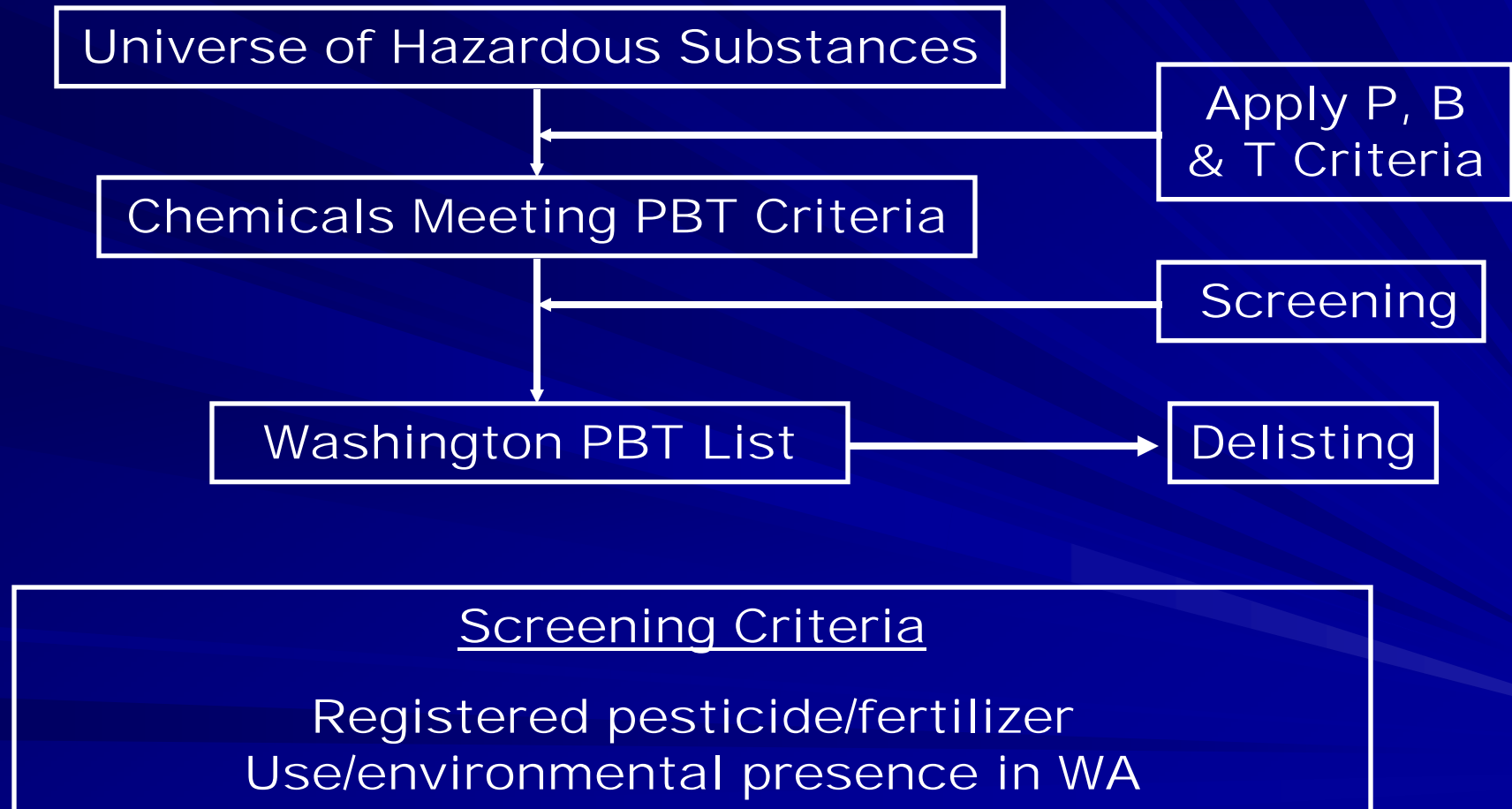
■ Evaluating three metals

- Mercury
- Lead
- Cadmium

Chemical Groups & Degradation Products

- Chemical Groups (PAHs, PCBs, etc)
 - Common structure/characteristics
 - Common sources/uses
- Degradation Products
 - Consider during listing process
 - May list parent substances

Screening Factors



WAC 173-333-330

Removing PBTs from the PBT List

- Scientific information developed subsequent to listing a chemical on the PBT list
- Clear and convincing evidence that chemical does not meet PBT criteria

WAC 173-333-340

Process for Revising the PBT List

- Periodic Review (at least once every five years)
- Rulemaking Petitions
- Public Notification on Preliminary Determination (CR 101)
- Rulemaking Process Used to Amend the PBT List

“....you have to look at it
objectively and make the tough
decisions...”

Theo Epstein
Boston Red Sox GM

WAC 173-333-310

The Initial PBT List

- Draft Rule includes an Example List
- Underlying Concept
 - Relevance to Actions in Washington
 - Not Limited to Chemicals on EPA List
- Next Steps
 - Complete Technical Comparisons
 - Review Comments on Criteria and Listing Factors
 - Prepare and Distribute Draft List

WAC 173-333-310

PBT Ranking

- Draft Rule includes Relative Ranking Concept
 - Category 1
 - Category 2
 - Category 3
- Appendix A
 - PBT Characteristics (40% weight)
 - Persistence (Sediment $\frac{1}{2}$ life)
 - Bioaccumulation (BAF/BCF)
 - Toxicity (ECOSAR - Chronic Value)
 - Uses or Potential Uses in Washington (20% weight)
 - Releases or Potential Releases in Washington (20% weight)
 - Environmental Concentrations (20% weight)

“....Its not over until its over...”

Yogi Berra

Part IV

Chemical Action Plans

2:00 – 3:30

Part IV - CAPs

- 400 – What is a CAP?
- 410 – Evaluation factors and processes Ecology to use to select PBTs for CAP
- 420 – Contents of a CAP
- 430 – Process Ecology will use to identify and prepare CAPs

400 – What is a CAP?

- A CAP is a plan that identifies, characterizes and addresses uses and releases of a specific PBT or a group of PBTs and includes recommendations on actions to minimize threats to human health and the environment by reducing and, where feasible, phasing out such uses and releases.
- CAPs may also include
 - recommendations for information gathering or additional monitoring that may be necessary to better understand a specific PBT.
- CAPs will address PBT releases from currently regulated point-sources, unregulated non-point sources, and individual sources.

Section 410 – Evaluation factors and processes Ecology to use to select PBTs for CAP

■ Purpose

■ Selection factors

- Relative PBT ranking (WAC 173-333-320)
- Opportunities for reduction
- Multiple chemical releases and exposures
- Sensitive population groups

■ Decision-making process

- Preliminary selection
- Public notice and comment
- Final decision

420 – Contents of a CAP

- Existing information on chemical
- Uses and releases
- Current management approaches
- Policy options
- Recommendations
- Technical feasibility
- Regulatory consistency
- Economic analyses
- Proposed implementation recommendations
- Performance measures
- Other

Section 430 – Process Ecology will use to identify and prepare CAPs

- Introduction
- Workplan/Scoping
- Advisory Committee
- Information Collection Phase
- Draft Recommendations
- Public Review and Comment
- Final Recommendations

Next Steps

"...If you don't know where you are going, you might not get there..."

Yogi Berra

November
17th
Meeting



December 8th
Meeting

- Revised Rule Language
- Revised List
- Supporting Analyses